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Coyne, J. C.

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Second Thoughts About Implementing Routine Screening of Cancer Patients for Distress

James C. Coyne, PhD.

University Medical Center, Groningen, the Netherlands

and

Institute for Health, Health Care Policy and Aging Research, Rutgers, The State University of New Jersey, USA

Correspondence:

James C. Coyne

University of Groningen, University Medical Centre Groningen

Department of Health Sciences, Health Psychology Section

P.O. Box 196

9700 AD Groningen

The Netherlands

Email: jcoynester@gmail.com

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Abstract

Recommendations for routine screening of cancer patients for distress lack evidence screening improves patient outcomes. Settings contemplating screening should consider other options for using the same resources. This article reviews evidence relevant to decision making and calls attention to limits in using screening instruments cross-culturally and for triaging patients for receipt of services. Whether screening is the best option depends on the patient population, culture and health system.

National and international professional organizations recommend and increasingly mandate routine screening of cancer patients for distress [1-4]. Professionals in many oncology settings are attempting to comply by implementing screening programs. In other settings, professionals are allowed to consider first whether available evidence is consistent with screening actually improving patient outcomes. They can decide whether to proceed with implementing screening or to find other ways to commit the resources that screening would require. In either case, clinicians, administrators, and policy makers do not have the benefit of a substantial body of evidence from randomized controlled trials demonstrating that routine screening for distress will lead to improved patient outcomes [5].

How to Evaluate the Evidence for the Efficacy of Screening

Screening for medical conditions is commonplace in clinical settings [6], and there are specific methodologies for evaluating the efficacy and cost effectiveness of screening for particular problems [7,8]. There was once a general assumption that clinicians should routinely screen if a means existed for problems that have significant clinical and public health implications. That conventional wisdom has undergone serious re-evaluation with the recognition that consultations with clinicians cannot accommodate screening for all problems. Moreover, much screening reveals problems for which intervention would not even be practical, cost-effective, or consistent with patient preferences. Screening can also lead to needless diagnostic and follow up procedures, overdiagnosis and overtreatment, with any benefits not balancing known drawbacks or even harm.

Attitudes toward screening vary greatly across cultures and health systems, with an extreme captured by direct-to-consumer marketing in North America of comprehensive computed tomography (CT) scans on demand to asymptomatic persons based on their ability to pay [9]. In response to such excesses, Choosing Wisely programs [10] have been endorsed by dozens of specialty and generalist medical societies to encourage re-evaluations of the efficacy and cost effectiveness of screening. This has led to recommendations against screening asymptomatic persons for dementia and ovarian, lung, and prostate cancer. Recommendations for routine screening require demonstration that screening has a better balance of benefits and potential harm at the patient and system level than patients simply having access to the same clinical resources without having to undergo screening. The burden of proof is on those who would recommend screening.

More than simply targeting an important clinical problem, screening must lead to improvement in patient outcomes. Thus, the World Health Organization recently advised that screening for intimate partner violence in general medical settings should no longer be done, because it did not lead to improved outcomes [11]. Routine screening for depression had previously been recommended and mandated in many general and specialty medical settings [12]. But when formally reevaluated, recommendations were next restricted in some countries to settings where resources are available for adequate diagnosis, treatment, and follow-up [13]. More recently, screening for depression is no longer being recommended except for settings with the necessary resources to ensure improved outcomes, with the presumption such settings are uncommon [14]. These revised recommendations are based on consistent evidence that without exceptional resources, routine screening for depression was not improving patient outcomes, and that where these resources are available, screening may add nothing to patient outcomes [15].

Is There Evidence That Screening for Distress Improves Patient Outcomes?

We undertook a systematic review of screening for routine distress in cancer patients [5], cognizant of the general standards used for evaluating screening in medical settings. We adopted the analytic framework of the U.S. Preventive Services Task Force (USPSTF) [16] in searching for evidence of (1) the efficacy of interventions for reducing distress; and (2) the efficacy of routine screening in reducing distress among cancer patients. For the first question we concluded that there is indeed some evidence that psychosocial and psychopharmacological interventions reduce distress. In answering the second question, we required randomized trials with patients assigned to the intervention receiving services based on score above a pre-set score on a screening instrument, whereas patients assigned to the control group could access the services without screening. We were able to identify only one such study [17] and it failed to demonstrate that screening improved outcomes. We concluded that, judged by established standards, there is insufficient evidence to recommend screening.

At least four other systematic reviews [18-21] have considered routine screening for distress. None adopted the same inclusion criteria as we did, with all considering a broader range of studies. The authors of all four included recognizable advocates of screening, but all nonetheless indicated a lack of quality evidence from randomized trials that screening improves patient outcomes. Yet, each review provided detailed guidance on how to implement distress screening in clinical practice. One review [21] concluded:

> Provisional work suggests that screening for psychological distress holds promise and is often clinically valuable, but it is too early to conclude definitively that psychological screening itself affects the psychological well-being of cancer patients.

The reviews variously indicated that screening may improve communication between patients and clinicians, stimulate discussions of psychosocial and mental health issues, and increase referrals to specialty services. These are not suitable surrogate outcomes. More discussions and better communication may be insufficient to achieve substantial

improvements in patient outcomes such as distress, psychological symptoms, and quality of life.

A number of these reviews included studies of interventions in which professionals used results of screening to structure discussions with patients that would otherwise be occurring, but without triaging, i.e., a score on a screening instrument did not determine whether the discussions would be held and which patients would be potentially offered services. This practice does not meet the formal definition of screening, but it is consistent with practices already implemented in some countries such as the Netherlands [3]. However, international guidelines indicate that a positive screen for distress should determine whether patients are offered a discussion. In countries such as the Netherlands, imposition of this guideline would require restricting the existing offering of discussions with professionals to patients who screen positive. While many patients who have significant unmet and addressable needs screen positive for distress, not all do. Many patients may have focal, remediable problems without registering general distress above a pre-set cutpoint. Furthermore, as seen in recruitment to clinical trials for evaluating interventions for distress, most patients who enroll do not have clinically significant distress, and so there would be a dilemma of whether they could still access such services. One of the unintended consequences of introduction of screening is that it could involve rationing of services and restricting of services to many patients who are currently accessing them.

A critical commentary on our systematic review [5] was solicited from some leading proponents of screening for distress, Barry Bultz and Linda Carlson [22]. We were given the opportunity to reply [23], creating one of the few debates that has occurred concerning the merits of screening for distress. Bultz and Carlson [22] criticized the conclusion of our review because it

> contravenes recommendations to screen broadly, which are based on prevalence studies demonstrating that patients experience distress in all of the physical, psychosocial and practical domains, with a real interplay among domains.

Recommendations of professional organizations about screening for distress have not followed established processes for developing systematic review–based consensus practice guidelines. It has been well-documented that practice guidelines from professional organizations are often biased and not evidence-based, particularly when for they are proposals for medical procedures that would require their members' services [24,25]. Criteria have been established for evaluating the processes generating guidelines [26,27]. Judged by those criteria, the process for developing recommendations for routine screening have been notably lacking of systematic review of the literature; transparency; composition of guidelines committee including formal involvement of patients, frontline clinician, and other key stakeholders; indicating of strength of evidence; articulation of guidelines in terms of strength of evidence; and external review.

Bultz and Carlson [22] also criticized us for adopting a narrow definition of distress and cite the broad definition of the National Comprehensive Cancer Network (NCCN) of distress as

> "a multifactorial unpleasant emotional experience of a psychological (cognitive, behavioral, emotional), social and/or spiritual nature that may interfere with the ability to cope with cancer, its physical symptoms and its treatment."

They further noted "Assessment recommendations include screening for specific problems which exacerbate distress in the physical, psychosocial and practical domains." In their own screening studies, Bultz and Carlson have operationalized as the simultaneous administration of different "screening tools" for general distress, anxiety, depression, suicidal ideation, pain,

fatigue, nutrition and weight, as well as concerns about accommodations for caregivers, transportation, parking, drug coverage, work and school, finances, and groceries [28].

This broadened definition poses problems for establishing criteria for evaluating the efficacy and cost-effectiveness of screening. In our reply [23], we noted that there are models for evaluating screening with multiple targets, and notably the United States Preventive Services Task Force (USPSTF) [16], which evaluates evidence on preventive services interventions in primary care.

> Primary care physicians are encouraged to screen for many different conditions, and many of them have psychosocial components (e.g., depression, intimate partner violence, alcohol abuse, smoking). Importantly, evidence for each of these screening interventions is evaluated separately. Otherwise, it would be impossible to determine which screening programs are beneficial and cost-effective. The same logic applies to psychosocial care in cancer settings. It may be the case that patients would benefit from being screening for many different problems. However, consistent with general principles of testing screening programs and expectations that scarce health care resources must be used wisely to be used effectively…[A] scattershot approach to screening, without any evidence of what works and what doesn't work, does not serve the best interests of patients. Appropriate targets for screening are medical problems for which screening can lead to effective intervention. Issues like parking or insurance problems can be identified by simply asking patients, but do not constitute screening. Once appropriate targets for screening are identified, the parameters for testing the screening program must be carefully considered.

Even without broadening, the term "distress" lacks a direct equivalent in many languages. The broadened conception of distress may prove difficult to operationalize and

implement outside of Anglo-American contexts, particularly where there has not been significant linguistic migration of the term, not only to clinicians but among patients [29-31]. Clinicians elsewhere soon discover that patients are bewildered by requests to complete a distress thermometer and that their responses are unreliable. Even with native English speakers, it is unclear to patients whether their responses to the distress thermometer should take into account physical symptoms and side effects of treatment or practical problems that patients do not assume can be solved within oncology services. Moreover, clinicians, particularly those with mental health backgrounds, are inclined to interpret the registering of such symptoms in terms of psychological morbidity.

The Validity of Screening Instruments and Cutpoints

Most guidelines indicate that screening for distress should make use of validated instruments with published cutpoints to identify distressed patients. Broadening of the rubric of distress has contributed to confusion as to what constitutes the gold standard for validating the performance of screening instruments and therefore how an optimal cutpoint should be set. There has been some effort to validate distress thermometers against problem lists and measures of unmet need. However, this effort is handicapped by measures of unmet need lacking psychometric development [32], with specific items greatly differing in their nature, clinical significance, and requirements for the resolution of the problem indicated by the item. Many tertiary comprehensive cancer centers draw from a wide geographic area, and so practical problems are commonly endorsed, such as transportation and parking, and housing for caregivers who accompany cancer patients to treatment. Any scale that combines items reflecting these problems with items indicating fatigue, inadequately treated pain or existential issues faces complex questions of weighing and prioritizing of these problems that will frustrate efforts at establishing basic psychometric characteristics [33].

Screening instruments are most often validated in terms of their performance as measures of emotional distress [34,35]. A number of screening instruments are available, but the most commonly recommended are the single item Distress Thermometer (DT) and, at least outside North America, the Hospital Anxiety and Depression Scale (HADS). The HADS is the most commonly used instrument to validate whether the shorter distress thermometer is sufficient as replacement for longer questionnaires and with what cutpoints. Yet both the DT and HADS have inexplicable wide variations in the cutpoints recommended in the research literature.

Mitchell's [35] comprehensive review of 19 studies analyzing the performance of the DT concluded that modest overall accuracy in detecting depression or anxiety disorders. A score below an established cutpoint is better at ruling out disorder than a score above a cutpoint is at ruling in the presence of a disorder. Depression and anxiety disorders have evidence-based treatments with psychotropic medications that require formal diagnosis to ensure that they are being administered to the appropriate persons. The implication of Mitchell's analyses are that appropriate use of the DT requires trained and credentialed staff for follow-up psychiatric diagnostic interviews and that the second stage interviewing will be inefficient in terms of identification of treatable disorder. Presumably, if such use of the DT is to result in improved patient outcomes, there has to be appropriate clinical resources for treatment and follow-up. Elsewhere, Mitchell [36] has noted

> No screening tool should be seen as an alternative to careful clinical assessment and management. Despite much interest in the development of short and ultra-short tools, data on validation and implementation are currently incomplete. Nevertheless, short methods seem to be at least as successful as the HADS, although substantially more efficient and hence more acceptable, and therefore may be a suitable initial method of assessment in busy clinical settings.

Mitchell's conclusions are valid, but his analyses overlook a serious problem in validation studies of the DT and in efforts to integrate them. In his analyses, Mitchell simply accepted the cutpoints that particular validation studies had obtained, with notable variation across studies. He committed the fallacy of assuming that for screening purposes, it is instruments that are being validated, not cutpoints. The reverse is true. It actually makes no sense to summarize a body of literature as offering evidence for the validity of screening, when the studies that are integrated relied on different cut points. Worse, without too many exceptions, these studies typically provide exaggerated estimates of the performance of the DT because they allowed the cutpoints the DT to freely vary or tested multiple cutpoints and chose the one that makes the DT looked most favorable. In either instance, such studies capitalize on chance and adapt to idiosyncratic characteristics of convenience samples or simple sampling error, reducing the generalizability. The practical clinical implication is that clinicians and program developers cannot expect that cutoffs for the DT available literature will be the most efficient for their purposes.

A number of reviews have evaluated the Hospital Anxiety and Depression Scale (HADS) as providing measures of anxiety and depression symptoms, as a means of screening for anxiety depressive disorders, and as a means of validating the DT as a short measure of distress against the longer one [34,35]. The same caveats apply about not using a screening instrument to make diagnoses from which treatment decisions will be made, but rather to rely on results obtained with the screening instrument as the first step in a two-step process in which positive screens of follow-up with an interview. However, there are more serious problems with the use of the HADS as a screening instrument, particularly crossculturally. Translations do not address formidable challenges to ensuring the resulting instrument adequately reproduces the content and structure of the original HADS [37]. The HADS has inexplicable variations in recommendations for optimal cutpoints, even using the original

English version [38]. Applications of various factor analytic techniques frequently fail to identify the intended separate anxiety and depression subscales, and results of factor analyses are highly dependent on the particular method chosen and the sample. At best, the items of the HADS converge on a single general distress factor. Examination of the content and response keys of the HADS reveal the source of the problems. British colloquial English of the 1950s was used in item construction, with an avoidance of description of psychiatric symptoms. In order to avoid patients ignoring item content and falling into a particular response set, developers of the HADS allowed response keys vary in content and be reversed from item to item in ways that patients will undoubtedly miss. We examined translations of the HADS and found evidence that translators either ignored these issues or improvised, calling into question the validity of the translations [37]. Overall, there is little to recommend the HADS either in its originally intended use in assessing or screening for depression and anxiety or as a measure of general distress, particularly in translation [38].

Finally, almost all validation of distress measures in oncology settings provide exaggerated estimates of their performance, because studies fail to exclude patients who are already known to have a psychiatric disorder or to already receiving mental health or psychosocial services [39]. Think of it: would we accept validations of mammography that failed to exclude patients with breast cancer or in treatment for breast cancer? In the few studies that exclude patients already receiving psychotropic medication, conventional screening instruments are found to be much less efficient in detecting otherwise missed psychiatric disorder [40].

Although recommendations for screening commonly recommend use of validated instruments with established cutpoints, evidence concerning “validation” is often weak and inconsistent. Revalidation of specific cutpoints in a particular setting can prove an ambitious

undertaking. Undoubtedly, to the extent to which screening is sustained in clinical settings, it is often informal, with choices of particular cutpoints intuitive and based on face validity.

Clinical Epidemiology and the Rationale for Screening.

Although less decisive than evidence from RCTs showing that screening improves patient outcomes, a variety of clinical epidemiological data can be referenced in making judgments about implementing routine screening of cancer patients for distress. Such data include comparative estimates of the rates of psychological symptomatology and diagnosable psychiatric disorder among cancer patients versus other medical populations; the trajectories of distress among cancer patients in routine care; the extent to which cancer patients actually prefer unmet needs uncovered in screening to be met within cancer care or by referral; and the extent to which patients who were screened and offered services actually receive those services. These data can either encourage implementation of screening or serve to raise questions whether screening is likely to provide substantial, clinically significant improvements in patient outcomes.

Studies of cancer patients using validated measures of psychological symptoms and psychiatric diagnoses based on validated semi structured interview [41] reveal comparable rates of symptoms and mental health problems to what is found in other specialty in general medical settings, including primary care [40,42]. Discussions of the need for implementing routine screening of cancer patients for distress typically assume high rates of symptoms and psychiatric disorder relative to other populations. This assumption may warrant a reevaluation.

Much of the heightened distress reported by cancer patients is self-limiting or resolves within routine cancer care without specialty psychosocial or mental health services [43,44]. The declining trajectory of distress is such that in large-scale screening studies [28,45] the overall rate of decline across groups, including control groups is substantially greater than any difference among interventions of varying intensity. Longitudinal observational studies of

patients who have been screened for distressed tend to assume that decreases in distress are attributable to the effects of screening, but this may not be the case.

A substantial proportion of the cancer patients indicating unmet needs do not wish to receive services within the context of cancer care [46, 47]. When asked, cancer patients variously indicate that they are already receiving services; believe they can solve the problems themselves; that concentrating on the substantial demands of treating their physical illness takes precedence over receiving psychosocial and supportive services; or simply that the services being offered to them are not needed, timely, or what they preferred [47,48]. Endorsements of problems on checklist do not necessarily represent *meetable* unmet needs in rates of endorsements may be poor estimates of the extent to which patients will accept services as a result of screening.

Only a minority of cancer patients who screen positive for distress subsequently receive services [45,49] and the limited available data suggest that screening is not a cost-effective way of getting cancer patients into services [49]. Presumably, the key mechanism by which routine screening would improve patient outcomes is that screening would increase uptake of services not otherwise received. There is a paucity of data that screening actually increases uptake of services. Yet such data should be considered crucial for evaluating prospects of screening for distress being likely to improve patient outcomes.

Screening for Distress Versus Alternative Use of Resources

Without adequate resources, the process of screening can degenerate into patients completing a screening instrument that is simply lost or placed in a paper folder or electronic record without further action. Alternatively, patients screening positive will be given referrals and sent off with no follow up as to the completion or the adequacy of the services received. Unless care is taken in implementing touchscreen screening for distress, interacting with a

touchscreen can become just another barrier to patients having ready face-to-face contact with peer and professional resources.

The large literature concerning improving care for depression suggests that to be effective, screening requires substantial resources including screening personnel and interviewers, staffing for making and rescheduling appointments and following up with patients, as well as accessible and affordable services matching patient needs and preferences. These conditions in turn require a coordinated, well resourced system with aligned incentives and an information system capable of fostering communication among diverse and potentially dispersed providers and with the patient. The obvious question becomes whether screening adds anything to such an infusion and organization of resources in terms of better patient outcomes.

Alternatives to screening include enhanced support, access to services, and follow up for patients already known to be distressed or socially disadvantaged [50], navigators or advocates for the socially disadvantaged, or simply providing ready opportunities for patients to discuss unmet needs with professional and peer counselors regardless of level of distress.

Conclusion

The absence of evidence that screening for distress improves patient outcomes is not the same as evidence that screening does not improve outcomes. However, the burden of proof lies with those who propose medical interventions like screening, not those who remain unconvinced of its benefits relative to alternative uses of the same resources.

Improvement in the outcome of patients who screen positive typically depends on referral to supportive services. In many medical settings, referrals are notoriously uncertain in their outcomes, and the fate of referrals—whether patients actually complete them and obtain

adequate services—is information that is typically not obtained; thus, the term “black hole of referrals” is applied in many settings to indicate that staff do not know what happens to referrals. It is known that low income and otherwise socially disadvantaged persons are much less likely to complete a referral. Any system depending on referrals needs to have features built in to make the extra effort for disadvantaged patients or else it will increase health disparities in receipt of services.

Regardless of the uniformity assumed by international guidelines, different cultures and different health systems will require radical differences if they go forward in the translation of guidelines into practice. Similarly, these cultural health system differences will also mean that potential unintended consequences of introducing screening will be different, as well as the pressing alternative use that the resources consumed by screening could be put.

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